

CLAIMS:

1. An implantable medical device having a connector header adapted to be coupled through the use of a tool to an electrical lead connector element of an elongated electrical medical lead, wherein:

the connector header is formed of a dielectric header body having at least one header connector bore and a header grommet aperture having a grommet aperture sidewall;

a connector block is disposed within the connector header having a threaded bore aligned with the header grommet aperture and a connector block bore aligned with the header connector bore adapted to receive the lead connector element when a proximal connector assembly of the elongated electrical medical lead is received in the header connector bore;

a setscrew is threaded into the threaded bore having a setscrew socket disposed to be engaged by the tool to enable rotation of the setscrew within the threaded bore to tighten the setscrew against or to loosen the setscrew from a lead connector element received in the header connector bore; and

a penetrable grommet is disposed within the header grommet aperture, the penetrable grommet comprising a generally cylindrical elastomer body having a grommet central axis and including a pre-formed resealable slit extending between opposed grommet inner and outer end walls enabling passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the pre-formed slit upon withdrawal of the tool, the elastomer body comprising a compound of silicone rubber filled with an additive decreasing the tendency of slit healing over time and facilitating passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the slit upon withdrawal of the tool.

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2. The implantable medical device of Claim 1, wherein the elastomer body of the penetrable grommet is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

3. The implantable medical device of Claim 2, wherein:
the header body is formed of a dielectric material of a first color, and
the additive colors the compound in a color contrasting from the first color providing a visible target for precisely aligning and inserting the tool through the central bore and the slit into operative engagement with the setscrew.

4. The implantable medical device of Claim 1, wherein:
the header body is formed of a dielectric material of a first color, and
the additive colors the compound in a color contrasting from the first color providing a visible target for precisely aligning and inserting the tool through the central bore and the pre-formed slit into operative engagement with the setscrew.

5. The implantable medical device of Claim 1, wherein the generally cylindrical elastomer body of the penetrable grommet includes a grommet sidewall extending between the opposed inner and outer end walls, the grommet sidewall formed having an irregular surface comprising a plurality of peaks and valleys that maintains fluid sealing contact with the cylindrical sidewall of the tubular header grommet aperture without adhesive therebetween.

6. The implantable medical device of Claim 5, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a nominal peak-to-peak outer diameter exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly

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that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

7. The implantable medical device of Claim 5, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a plurality of sealing rings having nominal sealing ring outer diameters exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

8. The implantable medical device of Claim 1, wherein a yield space is provided between the inner end wall of the grommet and the setscrew socket to accommodate the elastomer body of the grommet that is pushed inward by the tool advanced through the pre-formed slit.

9. The implantable medical device of Claim 8, wherein the yield space is provided at least in part by a recess extending into the inner end wall of the penetrable grommet.

10. An implantable medical device having a connector header adapted to be coupled through the use of a tool to an electrical lead connector element of an elongated electrical medical lead, wherein:

the connector header is formed of a header body formed of a material of a first color and having at least one header connector bore and a header grommet aperture having a grommet aperture sidewall;

a connector block is disposed within the connector header having a threaded bore aligned with the header grommet aperture and a connector block

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bore aligned with the header connector bore adapted to receive the lead connector element when a proximal connector assembly of the elongated electrical medical lead is received in the header connector bore;

a setscrew is threaded into the threaded bore having a setscrew socket disposed to be engaged by the tool to enable rotation of the setscrew within the threaded bore to tighten the setscrew against or to loosen the setscrew from a lead connector element received in the header connector bore; and

a penetrable grommet is disposed within the header grommet aperture, the penetrable grommet comprising a generally cylindrical elastomer body having a grommet central axis and including a resealable pre-formed slit extending between opposed inner and outer end walls enabling passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the pre-formed slit upon withdrawal of the tool, the elastomer body comprising a compound of silicone rubber filled with an additive that colors the compound in a color contrasting from the first color providing a visible target for precisely aligning and inserting the tool through the central bore and the pre-formed slit into operative engagement with the setscrew.

11. The implantable medical device of Claim 10, wherein the penetrable grommet disposed within the header grommet aperture is formed of a compound of silicone rubber compounded with titanium dioxide in a concentration of up to about two percent by weight.

12. The implantable medical device of Claim 10, wherein the generally cylindrical elastomer body of the penetrable grommet includes a grommet sidewall extending between the opposed inner and outer end walls, the grommet sidewall formed having an irregular surface comprising a plurality of peaks and valleys that maintains fluid sealing contact with the cylindrical sidewall of the tubular header grommet aperture without adhesive therebetween.

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13. The implantable medical device of Claim 12, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a nominal peak-to-peak outer diameter exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

14. The implantable medical device of Claim 12, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a plurality of sealing rings having nominal sealing ring outer diameters exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

15. The implantable medical device of Claim 10, wherein a yield space is provided between the inner end wall of the grommet and the setscrew socket to accommodate the elastomer body of the grommet that is pushed inward by the tool advanced through the slit.

16. The implantable medical device of Claim 15, wherein the yield space is provided at least in part by a recess extending into the inner end wall of the penetrable grommet.

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17. An implantable medical device having a connector header adapted to be coupled through the use of a tool to an electrical lead connector element of an elongated electrical medical lead, wherein:

the connector header is formed of a dielectric header body having at least one header connector bore and a header grommet aperture having a grommet aperture sidewall;

a connector block is disposed within the connector header having a threaded bore aligned with the header grommet aperture and a connector block bore aligned with the header connector bore adapted to receive a lead connector element when a proximal connector assembly of the elongated electrical medical lead is received in the header connector bore;

a setscrew is threaded into the threaded bore having a setscrew socket disposed to be engaged by the tool to enable rotation of the setscrew within the threaded bore to tighten the setscrew against or to loosen the setscrew from a lead connector element received in the header connector bore;

a penetrable grommet is disposed within the header grommet aperture, the penetrable grommet comprising a generally cylindrical elastomer body having a grommet central axis and including a resealable pre-formed slit extending between opposed grommet inner and outer end walls enabling passage of the tool therethrough into the setscrew socket for rotating the setscrew and sealing of the pre-formed slit upon withdrawal of the tool; and

the generally cylindrical elastomer body of the penetrable grommet includes a grommet sidewall extending between the opposed grommet inner and outer end walls, the grommet sidewall formed having an irregular surface comprising a plurality of peaks and valleys that maintains fluid sealing contact with the cylindrical sidewall of the tubular header grommet aperture without adhesive therebetween.

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18. The implantable medical device of Claim 17, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a nominal peak-to-peak outer diameter exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

19. The implantable medical device of Claim 18, wherein a yield space is provided between the inner end wall of the grommet and the setscrew socket to accommodate the elastomer body of the grommet that is pushed inward by the tool advanced through the pre-formed slit.

20. The implantable medical device of Claim 19, wherein the yield space is provided at least in part by a recess extending into the inner end wall of the penetrable grommet.

21. The implantable medical device of Claim 17, wherein the grommet aperture has a nominal inner diameter and the grommet sidewall is formed having a plurality of sealing rings having nominal sealing ring outer diameters exceeding the nominal inner diameter of the sidewall to provide a low pressure interference fit upon insertion of the penetrable grommet into the header grommet aperture, whereby a low, uniform, interference pressure is attained over a wide tolerance upon assembly that is maintained even if the inner diameter of the cylindrical sidewall of the tubular header grommet aperture changes over extended time periods.

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22. The implantable medical device of Claim 21, wherein a yield space is provided between the inner end wall of the grommet and the setscrew socket to accommodate the elastomer body of the grommet that is pushed inward by the tool advanced through the pre-formed slit.

23. The implantable medical device of Claim 22, wherein the yield space is provided at least in part by a recess extending into the inner end wall of the penetrable grommet.